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EXAMINER

DAVIS, DEBORAH A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1641

DATE MAILED: 11/19/2003

29

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/717,478

Applicant(s)

ANDERSON ET AL.

Examiner

Deborah A Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2003.
- 2a) ☒ This action is **FINAL**.      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-32 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9, 11-17, 22-28, 31 and 32 is/are allowed.
- 6) ☒ Claim(s) 18-21, 29 and 30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application):
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

1. The RCE amendment filed October 23, 2003 is acknowledged and has been entered. Currently claims 1, 3-4, 8-9, 16-17, 22-28 have been indicated allowable.

Claims 2 and 10 are cancelled. Claims 18-21 and 29-30 stand rejected.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 18 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly (WO96/13707) in view of Manfred Augstein (USP#5,665,310).

Connolly illustrates how to read the surface of a test strip with an optical reading apparatus. This apparatus contain a separate optical readhead that determines color and shade of a test strip while being inserted (pg. 3, lines 33-35). One or more light sources for high intensity light emitting diodes (LED) are located in housing to illuminate the test strip while a light detector or sensor is able to take a reading of light reflected from the surface of the test strip that can be adapted to generate or respond to particular wavelengths of light (pg. 17, lines 1-10). Connolly discloses the use of two wavelengths can allow one to define the pseudo endpoint algorithm, which can allow for

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an increased range of a chemistry reaction (pg. 21, para 3). In addition, Connolly discusses the use of multiple wavelengths to correct problems in positioning the strip in the apparatus (pg. 21, para 4). Connolly teaches an EEPROM unit that is connected to a microprocessor/microcontroller containing measurement parameters, software, calibration data and a means for recognizing a reagent on a test strip (pg. 17, 1<sup>st</sup> and 2<sup>nd</sup> para). The photometer includes a separate optical reader head (pg. 3, line 33) light emitting diodes (LED) are contained in a housing to illuminate the test strip containing the sample (pg. 17, lines 1-5). An immunoassay can be performed on the test strip using immunological reagents that generate specific signals when exposed to a target analyte (pg. 3, lines 21-23). When the proper amount of a sample is applied to the strip, the apparatus goes through three measurement cycles, with the third measurement determining the final density. The density is compared to a table of values through the use of an algorithm stored in the EEPROM (pg. 19, 2<sup>nd</sup> para). Chromophore indicators are used along with multiple wavelengths to better enhance the range of chemistry on a test strip (pg. 21, 2<sup>nd</sup> para). Also the use of fluorescent labels is used for analyte detection (pg. 14, table VIII). Once the analyte is determined on a test strip, it produces color (pg. 19, lines 12-16).

Although the apparatus of James Connolly comprises a reader head, he does not specifically point out the ability of the reader head to move.

However, Manfred Augstein teaches an apparatus for analyzing a sample on a test strip that comprises a measuring head. The measuring head moves along the test strip to measure the remission values of the test (col. 2, lines 26-40). The measuring

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head is moved over the test strip with the aid of a drive motor (col. 5, lines 15-23). The advantage of this move head is that test fields (test strips) can be evaluated with only one measuring head as it moves across (uniformly) to evaluate the sample (col. 4, lines 63-66). In addition, various test fields of a test element are examined by moving the measuring head along the direction of the test element (e.g. in a stepwise fashion) measuring each test section of the strip (col. 4, lines 26-32).

It would have been obvious to one of ordinary skill in the art to employ the movable measuring head of Manfred Augstein into the photometer of James Connolly to provide a head that is mobile in that it is able to read all sections of the test strip that contains the sample to be read.

4. Claims 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Manfred Augstein (USP#5,665,310) and in further view of Ralph S. Hernicz (USP#4,659,229).

See above teachings for James Connolly and Manfred Augstein.

Connolly and Augstein differ from the instant invention in failing to specifically disclose an aperture in a readhead and the use of fiberoptic bundles.

Hernicz teaches a readhead that contains an aperture (34) to allow light to transmit through (col. 4, lines 1-2). Hernicz also teaches the use of fiberoptic bundles (54 and 56) for illuminating a sample and measuring reflected light (Summary invention and Figure 3). Such a structure of optical head would provide a new and improved

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readhead for a spectrophotometer cable of more efficient measurements of multiple samples accurately, with reduced height sensitivity (Summary of the invention section).

Therefore, it would have been obvious to one skilled in the art at the time the invention was made to have provided in the readhead of Connolly an aperture and fiberoptic bundles as taught by Hernicz, in order to provide a new and improved read for a spectrophotometer capable of more efficient measurements of multiple samples accurately, with reduced height sensitivity. It would have been further obvious to employ the movable measuring head of Manfred Augstein into the photometer of James Connolly to provide a head that is mobile in that it is able to read all sections of the test strip that contains the sample to be read. With respect to the wavelengths relative to regions of the test strips, as recited in claims 11 and 12, one of ordinary skill in the art would have found it obvious to illuminate at a particular wavelength over a certain region of the test strip in order to optimize the measurement of the analyte on the test strip, depending on the structure of the test strip.

5. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over James Connolly in view of Manfred Augstein for reasons set forth above.

See teachings of James Connolly for the teachings of multiple wavelengths and parameter reading of an analyte. See also the teachings of Manfred Augstein for the mobile measuring head.

a. With respect to transmitting light onto the surface at an angle normal to the surface and measuring light reflected normally from the surface, the

specification does not give a special definition; therefore, the prior art will satisfy the instant claims. In addition, the combined references of Manfred Augstein and James Connolly provide for angle adjustments in the test strip and the mobility of the measuring head to obtain the optimized light transmission of a surface reading as desired. Especially since it held to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum adjustments of a process by routine experimentation." Id. At 458, 105 USPQ at 236-237. The "discover of an optimum adjustment result in a known process is ordinarily within the skill of the art." Application of Voesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

### ***Response to Arguments***

6. However, claims 18 and 21 remain rejected because the prior art of James Connolly in view of Manfred Augstein are applicable. Applicant's argument that the method of Connolly does not entail moving a reader head over the surface of the test strip and does not teach or suggest uniformly illuminating the surface of a test strip nor does Connolly teach or suggest measuring repetitions and illuminating steps at a

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plurality of positions on the surface of the strip nor determining and intensity or shape of an image is not found persuasive. James Connolly teaches reading a test strip at multiple wavelengths for several reasons; one such reason is to eliminate interferences from substances such as bilirubin and others that can give false readings (see Connolly, page 22, lines 1-5). Connolly also teaches high intensity light emitting diodes (LED) are located in housing to illuminate the test strip while the light detector or sensor is able to take a reading of light reflected from the surface of the strip (pg. 17, lines 1-10). With respect to determining the intensity or shape of the image, according to applicant's specification (page 30, lines 20-30), Reflectance and densitometers and other transmittance readers can be used to detect images. Therefore, it is the Examiner's position that the reader of Connolly can detect an image on the test strip. With respect to determining uniform illumination, Connolly teaches illumination of a test strip, and since there is not a particular definition in the instant specification of uniform illumination, it is the Examiner's position that the reflectance photometer of Connolly satisfies this limitation. Connolly does not teach moving a reader head over the surface of the test strip, but the reference of Augstein does and is addressed below. In addition, arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

7. Applicant's argument that the reference of Augstein does not teach or suggest a method that requires repeating measuring and illuminating steps at a plurality of



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positions on the surface of the test strip is not found persuasive. Applicant's argument that Augstein does not teach determining a parameter associated with the intensity or shape of the image, nor uniformly illuminating a test strip is also not found persuasive. As stated above, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The reference of Augstein is relied upon for a movable readhead that moves along the test strip to measure the test sections of the strip as recited in claims 18 and 21. In addition, the movable readhead of Augstein is moved across each section of the test strip in a stepwise fashion (uniform) (column 4, lines 63-66).

8. Applicant's argument that Connolly nor Augstein, singly or in combination, teaches or suggests taking measurements at a plurality of positions along the surface of the test strip, nor uniformly illuminating the surface of a test strip, nor determining the intensity or shape of an image is not found persuasive because Connolly and Augstein in combination teach and suggest the limitations of the instant claimed invention (see arguments above for Connolly and Augstein).

9. Applicant's argument that Connolly nor Augstein singly or in combination teaches or suggests taking measurements at a plurality of positions along the surface of a test strip is not found persuasive. Augstein teaches moving the readhead in a stepwise fashion covering each test section of the test strip (column 4, lines 26-32).

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10. Applicant's argument that Connolly nor Augstein does not teach or suggest measuring multiple positions of a test strip and that Augstein teaches measuring separate and different test fields separated by measuring openings is not found persuasive. Augstein teaches measuring a test strip at a plurality of positions that are separate test fields, a limitation not excluded from the claims and therefore satisfies this limitation.

11. Applicant's argument that the combination of Connolly and Augustein does not teach or suggest multiple light measurements made to determine an intensity or shape of the of an image is not found persuasive because Connolly teaches that multiple measurements can be made to eliminate interferences from substances such as bilirubin and other analytes. In addition, applicant's instant specification (page 30, lines 20-30), indicate that Reflectance and densitometers and other transmittance readers can be used to detect images. Therefore it is the Examiner's position that the multiple measurements of Connolly can determine the intensity or shape of an image on a test strip.

12. Applicant's argument that there is no suggestion by Connolly to carry out three measurements at each of a plurality of different positions for the purpose of measuring a particular image is not found persuasive. Connolly teaches different reasons for carrying out multiple measurements of a test strip with one being to eliminate interferences from substances such as bilirubin and others.

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13. Applicant's argument that neither Connolly nor Augstein suggest indicating the desirability of uniformly illuminating the test strip is not found persuasive for reasons aforementioned above.

Applicant's argument that neither Connolly nor Augstein teaches or suggests transmitting light onto the surface at an angle normal (or perpendicular) to the surface, and measuring light reflected normally from the surface is not found persuasive. The specification does not give a special definition for transmitting light onto the surface at an angle normal to the surface and measuring light reflected normally from the surface; therefore it is the Examiner's position that the prior art satisfies this limitation. In addition, the combined references of Manfred Augstein and James Connolly provide for angle adjustments in the test strip and the mobility of the measuring head to obtain the optimized light transmission of a surface reading as desired. Especially since it held to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of *Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum adjustments of a process by routine experimentation." *Id.* At 458, 105 USPQ at 236-237. The "discover of an optimum adjustment result in a known process is ordinarily within the skill of the art." Application of *Voesch*, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

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14. Applicant's argument that one of ordinary skill in the art cannot follow the teachings of Connolly to arrive at the claimed methods because Connolly teaches the desirability of particular angles that are contrary to the angles of the claimed method and modifying the angles taught by Connolly to arrive at the claimed methods would eliminate the benefit taught by Connolly of having the light sources at different is not found persuasive. Applicant's argument also goes on to say that to achieve the claimed method, one of ordinary skill in the art must orient the light at an angle normal to the surface, not at 40 or 50 degrees relative to the surface because that would eliminate the benefits taught by Connolly that result when the light sources are used at two different angles is also not found persuasive. The example given by Connolly of the detector being at "0" and the emitters of the same or different wavelengths are at different angles of 40 and 50 degrees, the tilting of a surface will result in a positive reading and a negative reading and is able to cancel out errors and is also used to eliminate interferences from substances on the test strip is only an example (page 5, lines 5-18). Although the reference of Connolly teaches multiple wavelengths and different angles, it is the Examiner's position that this does not exclude a wavelength at a normal angle and that Connolly satisfies this limitation.

15. Applicant's argument that Hernicz neither teach nor suggest moving a reader over the surface of a test strip nor uniformly illuminating the test strip. Hernicz does not teach or suggest transmitting light emitted from a light emitting diode through a fiberoptic bundle to the surface of a test strip. Moreover, Hernicz does not teach or

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suggest transmitting light emitted from any light source through a fiberoptic bundle to the surface of a test strip nor through fiberoptic bundles arranged to achieve uniform illumination and maximize reflected light nor does it teach transmitting light from a light source to a test strip. This argument is not found persuasive because Hernicz teaches an improved measuring head that contain fiberoptic bundles that are contained inside the measuring head. The primary reference of James Connolly teaches that LED (light emitting diodes) is located in the readhead. The teaching of transmitting light from a light source is the result of combined limitations of Connolly and Hernicz and are well known in the art.

16. Applicant's argument that claim 20 is unobvious over the cited references because the references do not teach or suggest moving the reader head to a second position over the surface of the test strip and carrying out three additional measurements at the second position. Further, neither the teachings of Connolly nor augstein teach or suggest carrying out three measurements at a second position over the test strips and would not be motivated to arrive at the claimed method. These arguments are not found persuasive. Connolly teaches multiple readings of a test strip to eliminate background interference of a sample analyte and therefore would include all positions of the test strip that would affect the analyte.

17. Applicant's argument that Hernicz does not teach the use of fiberoptic bundles for transmitting light from a light source but only from a sample on the test strip is not found persuasive because Connolly teaches the LED that are located in the readhead and the Hernicz is relied upon for the teaching of fiberoptic bundles. In response to

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applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the references of Connolly and Hernicz in combination supply the teaching of fiberoptic bundles and LED which can suggest to one of ordinary skill in the art to be an obvious modification.

Applicant's argument that if the reader head of Hernicz were to be modified such that the emitted light was transmitted by a fiberoptic bundle to the surface of the sample, the method of illuminating the sample would be changes and the shape of the reader head would be rendered irrelevant; and therefore the benefits resultant from the shape of the reader head would be eliminated. This argument is not found persuasive because The primary reference of James Connolly teaches the LED (light emitting diodes) are located in the readhead, how the fiberoptic bundles are coupled and the read head is shaped would be a matter of design choice that one of ordinary skill in the art would recognize wherein such designs can be modified. Therefore it is the examiners position that in light of the arguments presented above, the references of Connolly, Augstein and Hernicz teach or suggest the claimed limitations.

***Allowable Subject Matter***

18. Claims 1, 3-9, 11-17, 22-28 and 31-32 are allowed. Claims 31-32 depend from allowable claims 1 and 5 and are in proper claim language.

***Conclusion***

19. Claims 18-21 and 29-30 are rejected.

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1123



Deborah A. Davis  
CM1, 7D16  
November 13, 2003



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11/17/03